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The effectiveness of airway management in the pre hospital treatment of traumatic brain injury : a retrospective, observational study of pre hospital treatment of traumatic brain injury (TBI) in the Western Australian ambulance service

Joseph Cuthbertson
Edith Cowan University

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The Effectiveness of Airway Management in the Pre Hospital Treatment of Traumatic Brain Injury.

**A retrospective, observational study of pre hospital treatment of Traumatic
Brain Injury (TBI) in the Western Australian ambulance service.**

MSc Candidate (Human Biology)

Joseph Cuthbertson

**Faculty of Computing, Health and Science
Edith Cowan University**

**Principal Supervisor: Associate Professor Mel Ziman
Associate Supervisors: Mr. S. Johnston, Dr J. Thompson**

Biostatistical Consultancy: Dr Tapan Rai

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ABSTRACT:

There is concern over mortality and the potential for secondary brain injury in the head-injured patient. The use of advanced airway management and rapid sequence intubation in the pre hospital treatment of patients with Traumatic Brain Injury is controversial. Currently in St John Ambulance Service Australia (WA) Inc. three forms of pre hospital treatment are utilized to manage the airway of the adult head-injured patient. If attended by on-road paramedic staff, basic airway management is utilized unless the patient is unconscious and areflexic, in which case advanced airway management utilising endotracheal intubation or laryngeal mask insertion is authorised. In the critical care paramedic setting, the severely head-injured patient can be managed utilising paramedic initiated rapid sequence intubation techniques and ongoing sedation, paralysis and ventilation. There is a lack of data evaluating the risk and outcomes involved with these techniques when utilised to treat head-injured patients by paramedics from the Western Australian ambulance service. This study provides an updated evaluation of outcomes associated with airway management. The research framework was that of a retrospective, observational study of patients transported and treated between January 2004 and January 2009 in Western Australia. As the designated state trauma centre, all major trauma patients admitted to Royal Perth Hospital trauma unit with a head abbreviated injury scale > 3 transported and treated pre hospital by St John Ambulance WA paramedics from January 2004 to January 2009 were included. Hospital records of patient outcomes were matched with pre hospital records. Whilst challenges were faced in the collection of quality, usable data; modifications in analysis methodology allowed achievement of some, but not all objectives. The use of advanced airway management was associated with increased odds of survival (OR of 8.9, p value .046). Results of this study indicate a significant association between advanced airway management practice performed by paramedics and survival for patients suffering TBI. Further

research is recommended to accurately assess efficacy of practice of this skill set in the pre hospital environment.

DECLARATION

I certify that this thesis does not, to the best of my knowledge and belief:

- incorporate without acknowledgment any material previously submitted for a degree or diploma in any institution of higher education;
- contain any material previously published or written by another person except where due reference is made in the text of this thesis; or
- contain any defamatory material;

Signed : J Cuthbertson

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<u>TABLE OF CONTENTS</u>	Page
LIST OF ABBREVIATIONS	5
LITERATURE REVIEW	6
<u>INTRODUCTION</u>	6
<u>SIGNIFICANCE OF STUDY</u>	7
<u>BACKGROUND</u>	7
Pathophysiology of Traumatic Brain Injury	8
Traumatic Brain Injury in the setting of poly trauma	14
Western Australian paramedic practice of airway management	15
Scene time	20
International pre hospital airway management practices	20
SUMMARY AND THEORETICAL FRAMEWORK	24
HYPOTHESIS AND AIMS OF THE STUDY	26
RESEARCH PLAN AND METHODS	27
STATISTICAL ANALYSIS	29
ETHICAL CONSIDERATIONS	31
RESULTS	31
DISCUSSION	41
LIMITATIONS	41
CONCLUSION	44
REFERENCES	45
APPENDIX	49

LIST OF ABBREVIATIONS:

Arterial carbon dioxide levels	(PaCO ₂)
Arterial oxygen levels	(PaO ₂)
Glasgow Coma Score	(GCS)
Rapid Sequence Intubation	(RSI)
Traumatic Brain Injury	(TBI)

LITERATURE REVIEW

INTRODUCTION

Traumatic brain injury (TBI) resulting from motor vehicle accidents and other mishaps is the leading cause of death and disability in young adults [1]. In Western Australia, the annual incidence of traumatic brain injury is over 1600 [2]. Mortality from TBI is almost 20%, primarily occurring within 48 hours of insult. Those that survive have a high incidence of disability, with less than 10% making a full recovery [3].

The incidence of mortality and morbidity is also directly related to the occurrence of secondary injury post insult [3]. As such, the correct airway management applications can have significant impact on the prevention of secondary injury but these interventions also carry a level of risk. The assessment of incidence of known risk factors and their association with mortality has provided guidance for the development of pre hospital clinical practice guidelines.

The practice of pre hospital airway management has been questioned in previous studies, particularly for those suffering traumatic brain injuries [4, 5]. These studies are based predominantly overseas, in many cases the scope of practice, patient demographic, crew qualification are not comparable to local practice. There are currently three treatment methods being utilised to perform airway management on patients suffering TBI by St John Ambulance Service Australia (WA) Inc. Evaluation and comparison of these management techniques has provided insight into which treatment pathway provides better patient outcome.

SIGNIFICANCE OF THE STUDY

Head injury is a major source of morbidity and mortality amongst trauma victims. In hospital clinical trials thus far have failed to reduce neurone loss post head injury; so much so that trials in this area have dwindled as potential therapeutic options have been exhausted. Pre hospital therapies and strategies provide new opportunities to achieve improved outcome for such patients.

This study is therefore significant as it is the first to analyse Western Australian pre hospital airway management practices of traumatic brain injury. The study has provided insight and guidance into current practice, with recommendations for service consideration. As such it is of enormous immediate benefit to St John Ambulance Service Australia (WA) Inc, the major provider of pre hospital care for patients with TBI in Western Australia. Moreover, this study provides significant clinical evidence to direct future treatment strategies at a state, national and international level.

During the time frame of this study, airway management of the head-injured paediatric patient was performed utilising only basic life support maneuvers in the Western Australian pre hospital setting. The outcomes of which were not assessed in this study.

BACKGROUND

The brain on average forms 2% of total body mass but accounts for 20% of total oxygen and glucose requirements and 15% of cardiac output [6]. Cerebral blood flow is regulated by pH, blood pressure and arterial carbon dioxide levels (PaCO_2). Auto regulation responds to decreases in blood pressure, arterial oxygen levels (PaO_2), pH and increases in PaCO_2 , resulting in

vasodilation to increase cerebral blood flow. Auto regulation enables consistent cerebral blood flow through intracranial vasoconstriction and vasodilation in response to changes in mean arterial pressure and can only be maintained with an adequate perfusion pressure [7]. Cerebral perfusion pressure is the resultant pressure gradient of the mean arterial pressure applied against the intracranial pressure. This relationship can be described as:

$$\text{Cerebral perfusion pressure} = \text{Mean arterial pressure} - \text{Intracranial pressure} [7]$$

When perfusion pressure is inadequate, auto regulatory processes cannot compensate to adequately maintain cerebral blood flow [7]. This is highly significant when TBI occurs in the setting of poly trauma as in these instances increases in intracranial pressure, and/or decreases in mean arterial pressure, lead to decreases in cerebral perfusion pressure and consequent ischaemia [6, 7]. Monitoring of cerebral perfusion, mean arterial and intracranial pressure is unavailable in the pre hospital setting. Consequently, systolic arterial pressure is substituted as the value used to estimate adequacy of cerebral perfusion pressure. Best evidence has shown that a minimum systolic blood pressure of 90mm Hg is optimal for patients suffering TBI [7-9]. This value has been utilised due to its correlation with mean arterial pressure and, in addition to this, events of hypotension defined as a single episode of < 90mm systolic, have been shown to be an independent predictor of increased mortality in the setting of TBI [8].

Pathophysiology of Traumatic Brain Injury:

Traumatic brain injury, also known as head injury or intracranial injury is the result of physical trauma causing brain damage and can result from a closed or penetrating head injury. It is

classified as mild, moderate or severe and can also be divided into two separate categories - primary and secondary brain injury [6].

Primary Brain Injury: Primary brain injury occurs as a result of the initial traumatic insult causing damage to the brain tissue and associated vasculature [6]. The ensuing injury is dependent on the mechanism and severity of impact/event. As neural tissue has poor regenerative properties, recovery from primary insult is poor [6, 7].

Secondary Brain Injury: Secondary brain injury causing further damage to neural tissue follows on from the initial traumatic insult and can occur minutes or days after the event. Changes to intracellular and extracellular media cause additional injury to the brain. These changes include hypoxia/hypoxaemia, hypotension, mass effect, anaemia, hypoglycaemia and hyperglycaemia [6].

The occurrence of these changes pre hospital can reduce the effectiveness of hospital based treatment and may have a significant impact on patient outcome. Secondary insults of hypotension and hypoxia in particular have been shown to double mortality in TBI, and the occurrence of hypotensive events is estimated at 35% [10]. Pre hospital hypotension has been shown to be an independent predictor of mortality when occurring in patients suffering TBI [8]. Secondary brain injury in patients with severe brain trauma can be avoided or reduced by advanced trauma life support, which in instances includes the use of advanced airway management and Rapid sequence Intubation (RSI) at the scene and during transport [8, 11, 12].

Hypoxia: Airways management and maintenance of adequate ventilation are essential in preventing secondary brain injury in the head-injured patient. Brain swelling, caused by increased

cerebral blood volume secondary to cerebral vasodilation from hypercapnia, is a direct result of apnoea and/or poor respiratory effort following TBI. Manley and Knudson [11] found in a prospective study that hypotension, and not hypoxia, was associated with increased mortality following brain injury. Whilst identification of this outcome is relevant in terms of identifying treatment risk factors; this study was conducted in the hospital environment and consequently is not comparable to pre hospital management. Stocchetti and Furlan [9] investigated the incidence of hypoxaemia and hypotension in the pre hospital setting of the head-injured patient in a prospective study and found outcome to be poor for patients with arterial hypotension or arterial desaturation. This study was only conducted in the aero medical retrieval environment, where skill base, training and experience do not reflect that of their on road counterparts. In addition, Chi and Knudson [13] conducted a prospective cohort study of the incidence of hypotension and hypoxia in the pre hospital setting in patients with potentially survivable brain injuries. They found that hypoxia in the pre hospital setting significantly increased the odds of mortality after brain injury, and that the incidence of secondary insult following TBI is common and associated with disability. Many other studies have shown an association between hypoxia and increased mortality in patients with TBI [4, 9, 12, 14-16]. It would therefore seem appropriate that episodes of patient apnoea and hypoxia should be avoided in the pre hospital environment to reduce morbidity and mortality. Clinical practice guidelines for St John Ambulance Service Australia (WA) Inc paramedics in the treatment of head injury direct the application of oxygen, high concentration or 100% (ventilate if necessary), to maintain an oxygen saturation of at least 90% [17].

Hyperventilation: For many years therapeutic hyperventilation was a mainstay of treatment for patients suffering TBI. Hyperventilation has subsequently been shown to be detrimental to outcome for patients with TBI [18]. The incidence of hyperventilation can be controlled using

End Tidal Carbon Dioxide (EtCO₂) monitoring [19]. At St John Ambulance Service Australia (WA) Inc, EtCO₂ is only measured in intubated patients treated by critical care paramedics when transported by helicopter. Patients treated by on-road staff, including critical care paramedics not rostered to the helicopter, do not measure EtCO₂; hyperventilation is therefore minimized by maintaining strict control of ventilation rates. The incidence of inadvertent hyperventilation is unknown in patients treated by on-road staff as it currently cannot be measured. Warner et al [20] conducted a prospective cohort study examining the effects of pre hospital ventilation following intubation performed by paramedics on patients suffering multiple trauma with TBI or isolated TBI. On admission to hospital, the patients' blood gas was assessed for PaCO₂. Measurements outside the normal range were considered markers of hyper- or hypo-ventilation. Their results demonstrated an association between hypercapnia and increased mortality and therefore they concluded that pre hospital ventilation is associated with lower mortality following severe TBI. Current Western Australian pre hospital practice recommends normal ventilation rates in the setting of TBI.

Hypotension: Changes in haemodynamic status as measured by systolic blood pressure have been shown to be a significant predictor of increased mortality following TBI and should be avoided and prevented where possible [11]. This can be due to a reduction in cerebral perfusion caused by systemic hypotension. Winchell and Simons [21] conducted a retrospective case control study to determine the frequency and clinical impact of transient systolic hypotension in patients with severe head injury. This study was conducted in an intensive care unit after admission and found that transient hypotensive episodes were associated with mortality and decreased functional status in patients with head injury. Furthermore, the impact of this secondary insult was greatest in patients with less severe primary injury. In a retrospective study of traumatic brain injured patients, Jeremitsky and Omert [15] found that significantly worse

outcomes were associated with hypotensive episodes occurring in the first 24 hours post injury. In order to avoid this, current evidence recommends the maintenance of a systolic blood pressure of 90mm Hg [7]. Traumatic brain injury does not, by itself, cause isolated hypotension, unless it is a pre-terminal event. As such, all trauma patients should be managed with a view to minimizing the size and duration of any existing or potential hypotensive episode [7, 11, 22]. Clinical practice guidelines for St John Ambulance Service Australia (WA) Inc paramedics in the treatment of head injury directs the application of IV fluids to maintain a minimum systolic blood pressure of 90mm Hg [17]. However Davis and Murray have both found that the use of advanced airway techniques including rapid sequence intubation can inadvertently cause fluctuations in blood pressure [23, 24].

Mass effect: Intracranial pressure may rise following traumatic brain injury due to the mechanism of mass effect, as described by Monro-Kellie Doctrine [6]. This principle states that the cranium is an enclosed space comprised of the brain, cerebrospinal fluid and blood. Volume increases in one of these components leads to a decrease in another and a subsequent increase in intracranial pressure. A traumatic brain injury leading to the development of an intracranial haematoma or oedema causes an increase in intra cranial volume. In the initial stages, this is compensated for by the displacement of cerebrospinal fluid to the spinal canal. As this mass expands, the ability to displace cerebrospinal fluid is exhausted, intracranial pressure rises, with concomitant falls in cerebral perfusion pressure and cerebral blood flow. This sequence of events results in ischaemia and eventual herniation of the brain (see Figure 1 volume pressure curve) [6, 7, 22].

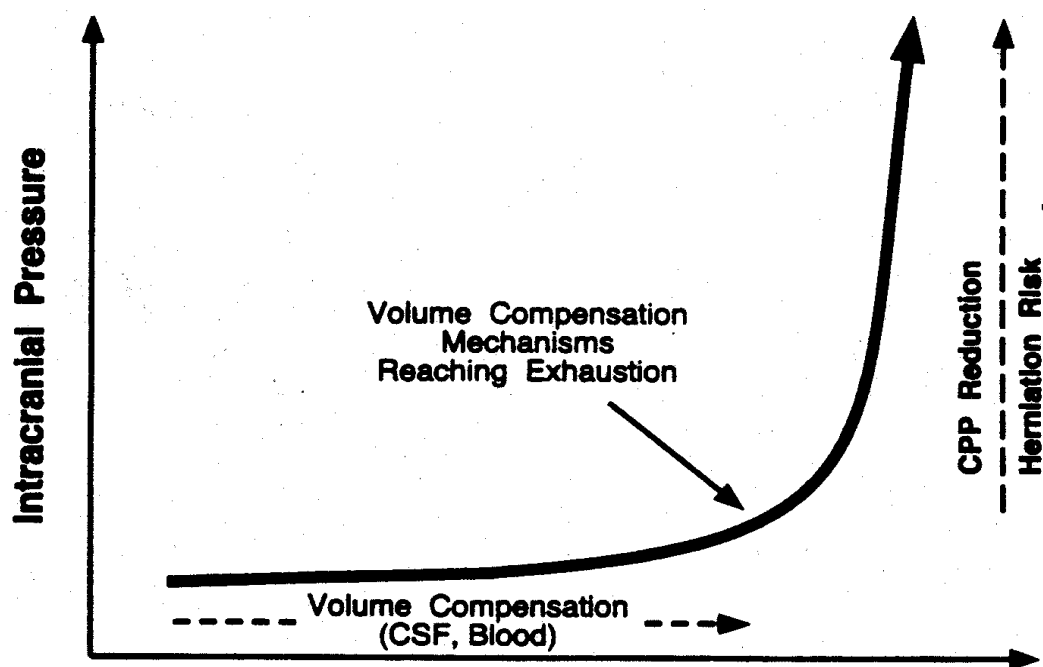


Figure 1

Volume – Pressure Curve[25]

Anaemia: Haemoglobin is essential for the delivery of oxygen to tissue. If the amount of haemoglobin falls, the oxygen-carrying capacity of the blood is reduced and hypoxaemia of vital organs occurs. In the setting of traumatic brain injury, prevention of blood loss from other, associated trauma is essential to reducing the effects of anaemia [7].

Hyperglycaemia / Hypoglycaemia: The impact of elevated or reduced glucose levels in the traumatic brain-injured patient can increase mortality/morbidity and decrease outcome. The brain is unable to store glucose and requires a continual supply to maintain cellular metabolism. When cerebral blood flow falls, so does the supply of glucose. Pre hospital treatment should focus on the prevention of hypoglycaemic events, which present a more immediate threat to patient care [7, 14, 26].

Central Nervous System Regeneration: The central nervous system has historically been known for its poor regenerative properties post injury. Current research is challenging this belief by demonstrating that neural stem cells exist in the adult central nervous system, that limited neurogenesis occurs throughout adulthood, and suggesting that injuries to the central nervous system may be repairable [27]. Early pharmacological therapy has traditionally been used for interventions such as RSI to prevent and reduce the effects of secondary insult; new drug therapy is now considering applications that include free radical scavenging, neuro-transmitter moderation and programmed cell death interference. Discovery of the existence of neural stem cells and neurogenesis in the adult brain will ultimately lead to new treatment modalities for therapy in the adult central nervous system that as yet remain to be determined [28]. Whilst this research is still in the early stages of investigation, promising results so far highlight the importance of quality pre hospital care to deliver patients in optimal condition for potential future interventions.

Traumatic Brain Injury in the setting of poly trauma:

It is common for brain injury to occur in conjunction with other traumatic injuries. The resultant mortality of people who suffer isolated head injury differs from those who suffer multiple injuries including head injury [3]. It is important to account for this difference when comparing the impact of pre hospital airway management techniques on patient mortality. The injury severity score is an anatomical scoring system that provides an overall score for patients with multiple injuries. The injury severity score takes values from 0 to 75, increase in score correlates with increased mortality, morbidity, hospital stay and other measures of severity [29]. The application

of the injury severity score in this research provided the ability to rank patient injury status equally when comparing the effects of pre hospital airway management techniques.

The revised trauma score is a physiological scoring system that provides a triage index for predicting serious injury and mortality in patients suffering trauma. The revised trauma score utilises the pre hospital values of Glasgow Coma Scale, systolic blood pressure and respiratory rate to rank patient injury status and has been shown to have a moderate to high ability to predict survival [30]. Application in this study of the revised trauma score before airway management established any discrepancy in the probability of patient survival post injury vs. actual survival when pre hospital airway management techniques were applied.

The Trauma and Injury Severity Score (TRISS) is the international standard for probability of survival calculation. TRISS is based on anatomical and physiological severity indicators and patient age. Utilisation of the TRISS analysis of trauma patients treated by paramedics provided a recognised international standard when examining local patient outcomes for comparison to other pre hospital systems [31]

Western Australian Paramedic Practice of Airway Management:

Western Australia has an area of 2 525 500 square km (33% of the total area of Australia) with a population less than 1.8 million, 80% of which live in and around Perth (approx. 1.4 million) [32]. Tertiary hospital care is only available in the metropolitan area with Royal Perth Hospital being the only level one trauma centre in Western Australia. Previous studies have revealed improved outcomes for patients with intracranial mass lesions due to trauma when transported to

neurosurgical care within 4 hours and for patients with severe TBI when directly transported within a state organised trauma system [33].

Three methods of airway management are currently utilised by St John Ambulance Service Australia (WA) Inc paramedics for the pre hospital treatment of head-injured patients. When treated by an on-road crew the patient receives basic airway management unless unconscious and areflexic, in which case advanced airway management may be attempted. Failing the ability of securing either basic or advanced airway management, cricothyrotomy may be attempted in the unconscious, areflexic patient where the airway is occluded. If treated by a critical care paramedic whilst seconded to the emergency response helicopter service, the patient may receive advanced airway management facilitated by rapid sequence intubation. Rapid sequence intubation refers to the swift facilitation of ideal intubation conditions using a combination of sedating and paralysing agents followed by intubation of the patient. This procedure is initiated and performed by the critical care paramedic when the patient is deemed to have a head injury with reduced Glasgow Coma Scale Score ≤ 8 , haemodynamic instability, and is unsuitable for flight without a definitive airway [17].

Basic airway management of the head-injured patient refers to treatment that does not involve the use of advanced airway management or rapid sequence intubation procedures in securing the patient's airway. This involves manual procedures (jaw thrust/chin lift), suction (as required), the use of appropriately sized oropharyngeal and nasopharyngeal airway devices (figures 2, 3), and ventilation with bag/valve/mask. Basic airway management is the minimum standard practice for paramedics for all airway management. Its use can be applied as the only technique for maintaining an airway, or it can be used prior to facilitation and preparation for further intervention, or when advanced airway management cannot be achieved [7, 17, 22].



Figure 2 Nasopharyngeal airway [17]

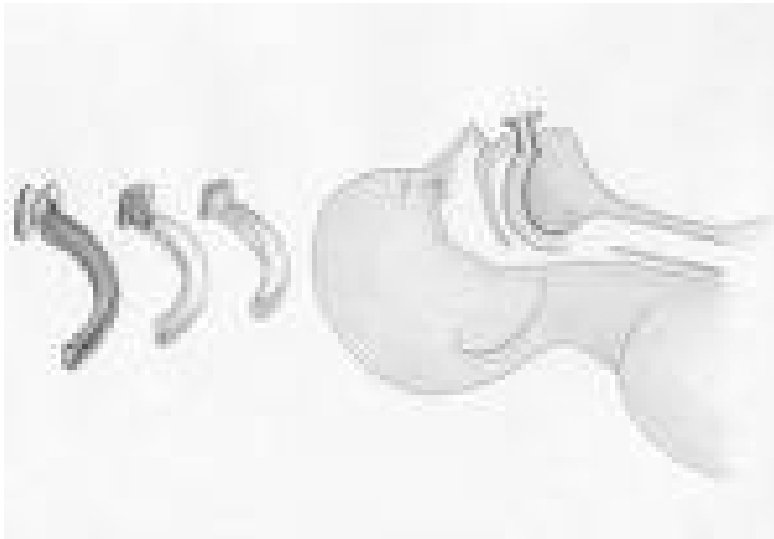


Figure 3 Oropharyngeal airway [17]

Advanced airway management of the head-injured patient by St John Ambulance Service Australia (WA) Inc refers to the utilisation of invasive airway devices that include laryngeal masks (figure 4), endotracheal tubes (figure 5), and surgical intervention including cricothyrotomy. Major concerns regarding the use of these devices refer to inadequate ventilation and oxygenation during attempts at intubation, incorrect placement of endotracheal

tubes and the adverse effects of hyperventilation [5, 9, 18, 24, 34-41]. The usage of advanced airway management, in particular endotracheal intubation, can only be achieved where airway reflexes are absent. As such, when this occurs in the setting of severe traumatic brain injury the prognosis of outcome is likely to be poor regardless of choice of airway management [42]. Previous studies have demonstrated conflicting results in patient outcome with traumatic brain injury treated with advanced airway management, with some suggesting that the use of these techniques for the treatment of traumatic brain injury is detrimental to patient outcome [43, 44]. However, these results should be interpreted in the context of the local emergency setting and are influenced by factors such as organisational design, clinical practice, training, experience and equipment. Davis et al. [45] investigated the impact of pre hospital endotracheal intubation on outcome in moderate to severe traumatic brain injury in San Diego County (USA). Of the 13 625 patients studied, survival was found to be higher for non-intubated patients vs. their intubated counterparts. Logistic regression was used to adjust for age, gender, mechanism of injury, GCS, head abbreviated injury scale, ISS and the presence of hypotension. Further analysis of the number of non-intubated patients that were later intubated at hospital and the method of intubation (i.e. the use of RSI) remains to be clarified.

Recent international research has also demonstrated similar findings. Bukur et al.[56] investigated the Los Angeles County Trauma System Database for all patients > 14 y of age with isolated moderate to severe TBI admitted between 2005 and 2009. Demographic characteristics and outcomes were compared between groups. Multivariate analysis was used to determine the relationship between pre-hospital endotracheal intubation and mortality. After adjusting for possible confounding factors, multivariable logistic regression analysis demonstrated that pre hospital intubation was independently associated with increased mortality (AOR 5, 95% CI: 1.7-13.7, P = 0.004).

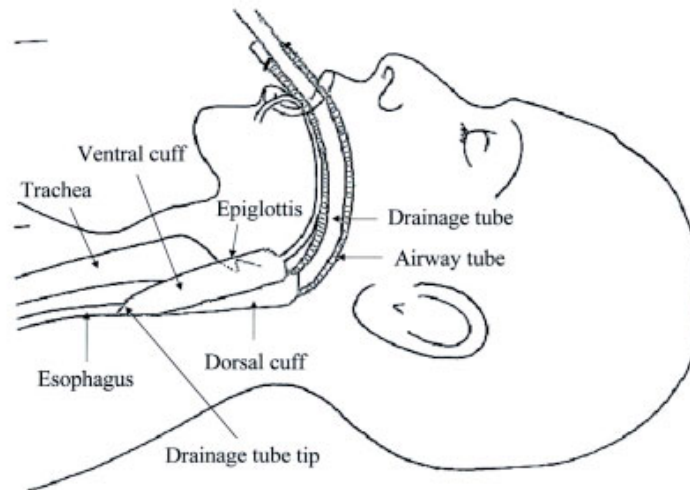


Figure 4 Laryngeal mask airway [17]

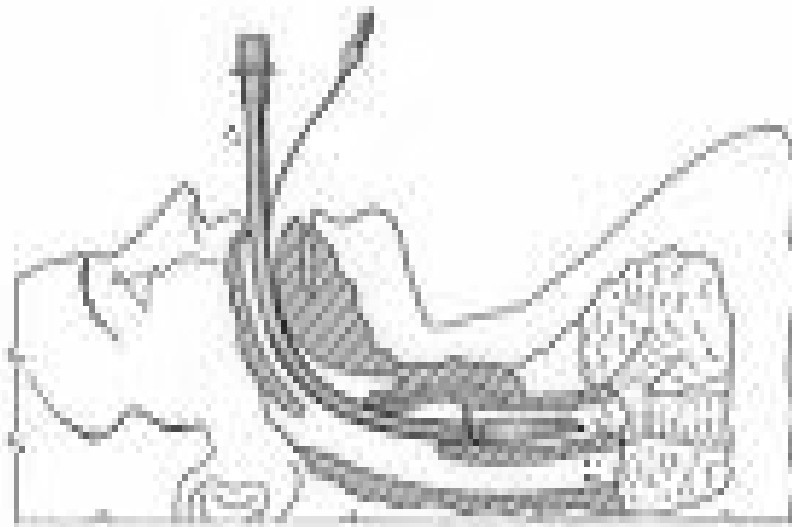


Figure 5 Endotracheal tube [17]

The primary motivation for implementing rapid sequence intubation by West Australian critical care paramedics is to enable intubation of adult, head-injured patients for helicopter transport when it is not clinically appropriate to transport without intubation. This is due to the difficulty and safety risks associated with managing a combative head injured patient in flight [17]. Rapid

sequence intubation is considered to be the procedure of choice for maintaining and protecting the airway of the head-injured patient [4, 9, 11, 41]. Several studies have shown that paramedics can safely and effectively perform rapid sequence intubation, especially when conducted by small groups of paramedics who have received additional training and experience [37, 38, 46, 47].

Scene Time:

Current teaching of pre hospital practice advocates minimal scene/treatment time and transportation to definitive care. The validity of invasive pre hospital practices has been questioned on the basis of extended scene times being detrimental to outcome. Carr et al. [48] investigated the time cost of pre hospital intubation and intravenous access in trauma patients. Using a large retrospective data set analysis they found that intubation was associated with an increased scene time of 2:36 to 3:39 minutes. Western Australia due is an expansive area and tertiary care is restricted to the Perth metropolitan area. The implications of extended scene times could be significant in reference to practice in Western Australia; however limitations in available pre hospital clinical data meant that this study could only assess care performed in the metropolitan setting. This, along with other poor data availability presented limitations to the findings of this study.

International pre hospital airway management practices:

Previous international studies have identified that differences between emergency medical service structures, training and protocol creates difficulties when comparing patient care and outcomes [10, 49]. This situation also occurs at a national level, where the level of training and standard of practice of pre hospital staff varies between states [34]. Furthermore most organisational systems display a low capacity to support invasive airway skills maintenance [50].

In this setting it could be postulated that poor outcomes are a consequence of poor procedure usage, rather than the procedure *per se* as a cause of harm.

The OPALS major trauma study was a before/after, system-wide controlled clinical trial conducted in 17 cities in Canada. It evaluated the impact of advanced life support provided by paramedics on survival and morbidity in patients suffering trauma. Its findings were that advanced life support skills (advanced airway management and intravenous fluid therapy) did not decrease mortality or morbidity for trauma patients; in particular intubation in the field was associated with higher mortality. It also found that mortality was greater where advanced life support skills were utilised in patients with a Glasgow coma score <9, which in the setting of trauma is usually indicative of a head injury [51]. Lockey et al. [43] investigated the outcome of patients intubated pre hospital without muscle relaxants or anaesthesia following trauma and found that where airway reflexes were absent only 1 in 486 patients survived. Conversely, Winchell et al. [38] found that the use of advanced airway management, without neuromuscular blockade or sedative (as utilised in rapid sequence intubation) by pre hospital ambulance staff was associated with higher survival rates. These findings are particularly relevant in the context of this project where the impact of basic and advanced airway management skills and rapid sequence induction will be examined in the setting of the head-injured patient, and demonstrate the need for further research to elucidate ways of improving patient outcome through better, evidence-based practice.

There is more to this story however, as other studies, also conducted in Canada, provide conflicting views. Mitchell et al. [52] compared outcomes of major trauma patients transported to a tertiary trauma centre by either air or road using Trauma and Injury Severity Score (TRISS) analysis. This found a significantly higher survival rate (25% reduction in mortality) in major

trauma patients transported by helicopter utilising critical care paramedic versus their on-road counterparts. The reason suggested for this variance is the superior skill of critical care paramedics.

Previously identified criteria for successful pre hospital airway management programs at a national and international level include robust training and skills maintenance, strong medical oversight, appropriate monitoring equipment and highly developed protocols. Fakhry and colleagues [41] retrospectively analysed patients suffering TBI treated with RSI by flight paramedics for performance improvement data. They concluded that a small group of highly trained paramedics with strong clinical oversight can safely perform RSI with high (96.6%) rates of success. Similarly, in a recent prospective, randomised controlled trial Bernard et al.[53] demonstrated highly successful paramedic RSI rates (97%) with significant improvements in functional outcome at 6 months follow up when performed by highly skilled intensive care paramedics compared to hospital intubation. Davis et al. [47] demonstrated improved success rates after prospective evaluation of paramedic administration of neuromuscular paralysis agents as part of an RSI protocol.

Bernard [34] reviewed pre hospital practice of airway management in the setting of severe head injury across Australian ambulance services. His findings demonstrated variability in the pre hospital treatment of traumatic brain injured patients between states and territories. The recommendation from this review is that RSI, whilst appropriate for critical care trained paramedics conducting aero medical retrieval, had yet to be validated for on-road usage and that advanced airway management should only be utilised where upper airway reflexes are absent. Bernard followed this review with a randomised controlled trial where patients suffering suspected traumatic brain injury were randomly allocated to RSI or standard treatment groups by

on-road paramedics[53]. Results of this study concluded that patients with severe TBI should undergo prehospital intubation using a rapid sequence approach to increase the proportion of patients with favourable neurologic outcome at 6 months post injury. This study was not without limitation however. In reporting a risk ratio of 1.28; with 95% confidence interval (1.00-1.64) it should be noted that the value of no effect when reporting risk ratios (1) demonstrates that the outcome could be due to chance alone. Furthermore the authors note in the paper that many participants meeting trial criteria were incorrectly randomised and that if one of the participants had been randomised to no RSI then the analysis would have reported against the reported findings.

International research examining patient outcome when treated with RSI for TBI is also conflicting. Davis et al. [54] found a 9 % increase in mortality in patients treated with RSI vs. historical non-intubated controls, whereas a retrospective analysis by Bulger et al. [55] found an increase in survival and outcome for patients treated with RSI pre hospital. Davis [42] conducted a further review of current literature and also found that available evidence was conflicting and inconclusive, but recommended that suboptimal performance of invasive airway management may outweigh procedural benefit and that more specific patient selection criteria for intervention may improve outcomes.

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SUMMARY AND THEORETICAL FRAMEWORK

A conflict continues to exist in the literature as to whether basic, advanced airway management or RSI is most appropriate in the pre hospital setting of traumatic brain injury and therefore how airway management is best performed. What is clear is that patients suffering a head injury require pre hospital intervention if their airway is at risk. When assessing the most appropriate method of securing the patient's airway, risk factors of bradycardia, excessive scene time, inadvertent hyperventilation, hypoxia and hypotension must be accounted for to ensure patient safety.

Furthermore, when comparing available literature regarding airway management in the pre hospital setting against Western Australian practice, several issues need to be considered. The Western Australian Ambulance Service does not operate a tiered ambulance service structure. In many Ambulance services practitioner levels are defined by scope of practice. Advanced airway management and RSI are usually only performed by the highest trained personnel within a service. Comparably in Western Australia, advanced airway management is practiced by all paramedics and RSI is only performed by critical care paramedics when seconded to the helicopter retrieval service. Consequently, there is a significant difference in training and experience between personnel within the Western Australian Ambulance service practising these techniques and this issue needs to be considered when evaluating standards of practice with other services in Australia and worldwide.

The evaluation of patient outcomes relative to this research has provided guidance in the formulation of clinical practice guidelines that reflect the weight of available evidence in reference to local population characteristics and WA Ambulance services.

In 2007 Elm and associates [49] published a systematic review of the current evidence for pre hospital intubation of patients with traumatic brain injury. Their findings indicated that the low methodological quality and inconsistency of study results prevented recommendation on pre hospital intubation. Further recommendations regarding future research include recording of severity of TBI and concomitant injuries using standard classification schemes, clear definition and description of control interventions, collection of data on respiratory and ventilation measures during the pre hospital period and upon hospital arrival and the use of validated outcome measures. This research project has addressed these recommendations by directly examining mortality and its association with procedural risk factors.

Hypothesis and Aims of the Study:

Hypothesis:

The use of intubation results in improved outcome relative to basic airway management, when utilised in the pre hospital treatment of patients with TBI by appropriately qualified and trained paramedic officers.

Aims:

Aim 1:

To assess the difference in outcome of TBI patients receiving intubation or basic airway management when matched for injury severity.

Aim 2:

To assess the incidence of hypotension and hypoxia and their association with mortality in patients suffering TBI when basic airway management, advanced airway management or critical care paramedic initiated rapid sequence intubation techniques is performed by Western Australian Ambulance paramedics.

RESEARCH PLAN AND METHODS:

Patient Data:

The research framework was that of a retrospective, observational study of patients transported and treated between January 2004 and January 2009 in Western Australia. As the designated state trauma centre, all major trauma patients are transported to Royal Perth Hospital, where a trauma registry records assessment and treatment details for all admitted patients. All patients admitted to Royal Perth Hospital trauma unit with a head abbreviated injury scale > 3 transported and treated pre hospital by St John Ambulance WA paramedics from January 2004 to January 2009 were included. Hospital records of patient outcomes were matched with pre hospital records.

Data elements included:

1. Date of case
2. Patient age and sex
3. Response time
4. Scene time
5. Transport time
6. Revised trauma score on first pre hospital assessment
7. Patient physiological measurements (GCS, heart rate, blood pressure, respiratory rate, SpO₂) on scene arrival, scene departure and hospital arrival.
8. Airway management utilised (basic, advanced or RSI)
9. Patient PaCO₂ measured by blood gas analysis on hospital arrival.
10. Patient injury severity score.
11. Patient trauma and injury severity score.
12. Patient survival to discharge
13. Total number of patients transported

Tables containing data for each of these elements were created. Each field in these tables contained data for statistical analysis. The tables were extracted and analysed for statistical significance utilising Statistical Package for the Social Sciences (SPSS version 17). A flowchart summary of the methodology is included in appendix 1.

Missing Data:

Record keeping at St John Ambulance WA Inc is required and stored for each patient, being a user pay system. The State Major Trauma Unit specifically tracks all injured patients with a head abbreviated injury scale > 3 , this is also part of this study's inclusion criteria. Consequently, very low levels of missing values were expected. If data is missing then hospital and/or ambulance case records were accessed to cross check for error. Missing values for specific variables were coded by a specific character to delineate them as such. Unfortunately whilst operational data from pre hospital clinical records was available, in many cases the clinical data capture was poor resulting in missing in large quantities for specific variables. As a consequence they were excluded from analysis.

Clinical inclusion criteria:

- Patients admitted to Royal Perth Trauma Unit with a head Abbreviated Injury Scale > 3 transported and treated pre hospital by St John Ambulance Service (WA) Inc during the period January 2004 to January 2009.
- Age ≥ 18 years.
- Application of pre hospital airway management

Clinical exclusion criteria:

- Patients deceased before hospital arrival.
- Age < 18 years.
- Commencement of Cardiopulmonary Resuscitation before hospital arrival.

Main Outcome Measures:

- To measure differences in mortality measured by survival to discharge between patients with TBI receiving pre hospital basic airway, advanced airway or RSI treatment.
- To measure the incidence of pre hospital hypotension (measured by systolic blood pressure) between patients with TBI receiving pre hospital basic airway, advanced airway or RSI treatment.
- To measure the incidence of pre hospital hypoxia (measured by SpO₂) between patients with TBI receiving pre hospital basic airway, advanced airway or RSI treatment.
- To measure the incidence of pre hospital hyperventilation (measured by respiration rate and PaCO₂ on admission) between patients with TBI receiving pre hospital basic airway, advanced airway or RSI treatment.

Statistical Analysis:

On average, St John Ambulance Service Australia (WA) Inc manages 100 cases of severe traumatic brain injury per year (approximately 30 who received advanced airway management or rapid sequence intubation and 70 who received basic airway management). Thus over the period

January 2004 – January 2009 the total number of patient cases expected to be reviewed as part of the study was 150 who received advanced airway management or rapid sequence intubation and 350 who received basic airway management. A sample size calculation was conducted utilising a Cox regression statistical power analysis by Peduzzi et al[57], the minimum calculated cases required being 483. Over the period of this study (January 2004 – January 2009) the total number of patient cases received for analysis as part of the study was 3293.

To account for statistical differences between groups, binary logistic regression analysis was used to control for variables and analyze their potential relationships to outcome (survival). P values of < 0.05 were considered statistically significant.

St John Ambulance WA Inc does not operate a tiered ambulance service as do other Ambulance services; only paramedics are authorised to perform airway intervention. All paramedics receive ongoing training education to evaluate and maintain standards of practice. Critical care paramedics are more experienced and receive higher training. The RSI skill set they provide is only available whilst rostered as a flight paramedic, in this environment they attend a high proportion of rural, pre hospital trauma within approximately 300 km of Perth and utilise the RSI intervention in the majority of these cases. When comparing this treatment group to others this will present as a confounder due to the difference in skill of the paramedic, and the differences in the technique used. However, it was the belief of this author that it is important to include this group to assess whether the extra investment in training, skills and equipment results in better outcomes. Unfortunately none of the reported cases documented use of this practice and consequently no analysis on this area could be performed.

Ethical Issues:

This study was reviewed by the Human Research Ethics Committee of Edith Cowan University and Royal Perth Hospital prior to commencement.

Informed consent: Due to the retrospective nature of this study, where treatment had already occurred, informed consent, dependency, potential for harm and stopping rules did not apply.

Confidentiality: Confidentiality of the patients who are enrolled in this study was very important to the researchers. Participant confidentiality was assured by the use of a unique identification code number. All data from this research (hard and electronic) is stored according to National Health and Medical Research Council (NHMRC) guidelines in a protocol approved by the ECU Human Research Ethics Committee.

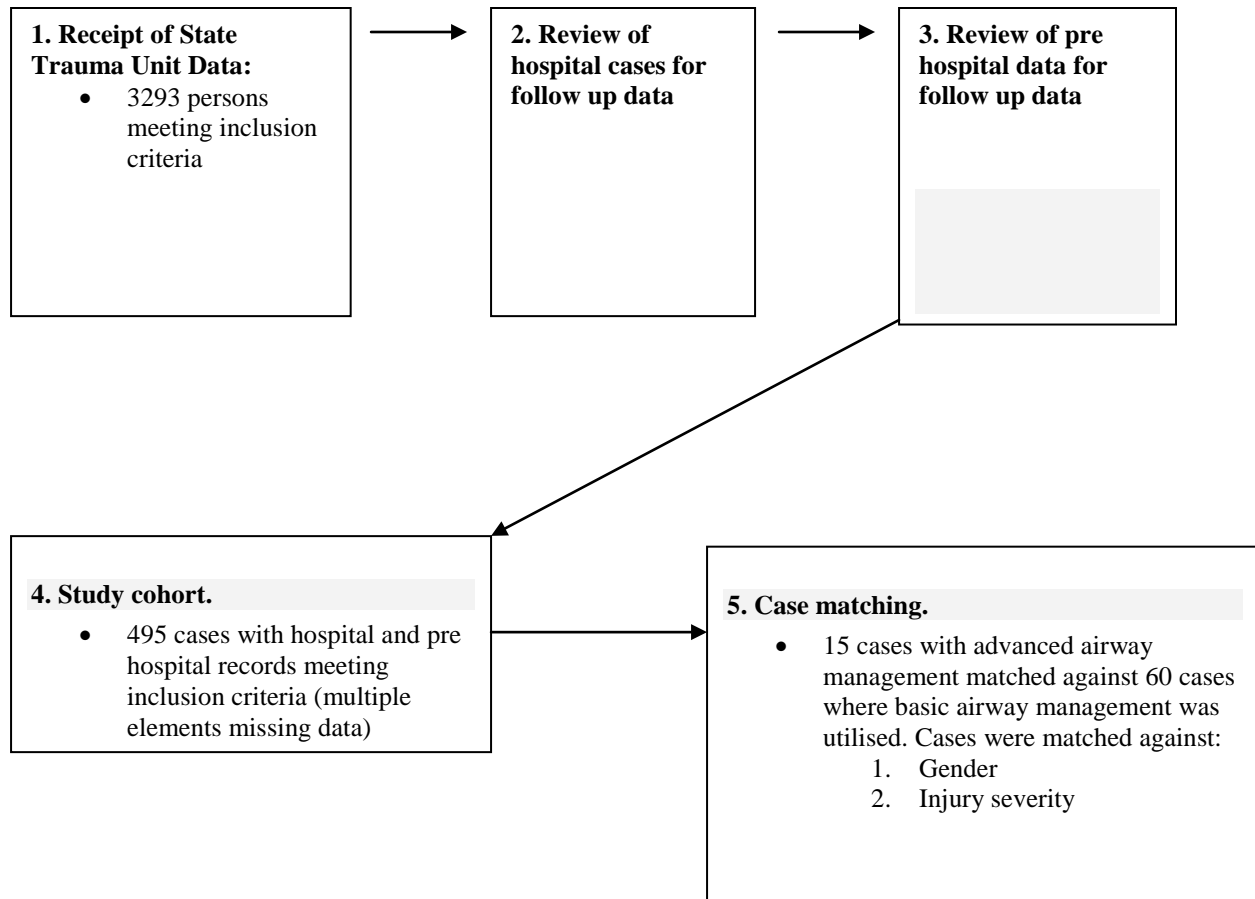
Results:

Data for this study was obtained from the Royal Perth State Trauma Unit database as a retrospective observational study of persons with major trauma including traumatic brain injury (TBI). Pre hospital information was gathered for all patients from the State Trauma Unit database. Criteria for inclusion in this study was: a) having sustained TBI between 2004 and 2009, with a head/neck AIS score >3, b) treated by St John Ambulance WA Inc staff, c) being at least 18 years of age when injured, and d) did not suffer cardiac arrest prior to hospital arrival, or receive CPR.

Participants: Selection and Characteristics

All data used in this outcome study were extracted from the Royal Perth Hospital State Trauma Unit database. The study base began with the 3293 persons admitted with TBI. Loss to follow up within hospital and identifying cases with complete pre hospital records resulted in a significant loss of usable data, only 495 cases were available for analysis.

Figure 6: Analysis process summary.



PATIENT DEMOGRAPHICS

Patient demographic details were extracted from the raw data to provide an overview of findings and limitations. The data was disproportionate in key areas of gender distribution and clinical intervention (tables 1 and 2). Further biostatistical review and modelling described below was required to account for these findings.

Table 1. Survival by Gender

	Male	Female	Total
Survived	290	97	387
Died	71	37	108
Total	361	134	495

Table 2. Survival by Intervention

	Advanced life support	Basic life support	Total
Survived	7	380	387
Died	8	100	108
Total	15	480	495

Clinical findings extracted from the raw data also presented challenges. Whilst some variables were well captured (table 3), others which are known confounders when assessing outcome related to TBI and pre hospital airway management were poorly recorded.

Table 3. Clinical Variables

Variable	Age	Response time	Scene Time	ISS	TRISS	SpO2	BP	Pulse	GCS	PaCO2	RR	RTS
N =	495	214	210	495	455	159	453	483	493	67	473	425
Missing	0	281	285	0	50	336	42	12	2	428	22	70
Average	49.56	5 (mins)	12.15 (mins)	27.16	.80	94.5%	127.32 (mmHg)	86.9 (bpm)	10.52	44.46 mmHg	19.3 (rpm)	6.58
Median	46	2.78 (mins)	11.4 (mins)	26	.92	97%	130 (mmHg)	86 (bpm)	13	43 mmHg	18 (rpm)	7.84
Standard deviation	24.945	4.86	6.09	10.985	.273	6.387	41.8	25.902	4.472	12.984	6.838	1.839
Range	83	10	46.2	59	1	40	260	200	12	63	56	8

What can be demonstrated from this data are findings related to known risk factors for patients suffering TBI. Average scene and transport time was minimal in comparison to accepted pre hospital standards of practice[7], recorded vital signs also demonstrated that hypoxic events (SpO2 94.5%) were largely avoided. Blood pressure recording demonstrated a large standard deviation (41.8 mm Hg). Whilst the mean blood pressure found that hypotension (BP 127.32 mmHg) was primarily avoided, the large standard deviation demonstrates that hypotensive events occurred. This is of concern given that previous research identified in the literature review found that hypotensive events are a significant cause of increased morbidity and mortality. Whilst these findings are positive they should be interpreted with caution due to the amount of missing data for some variables and the uneven proportion within the data. The below graphs (figures 7, 8, 9) provide an overview of age, response time and injury severity score to demonstrate the uneven distribution of data within fields.

Figure 7. Age in Years

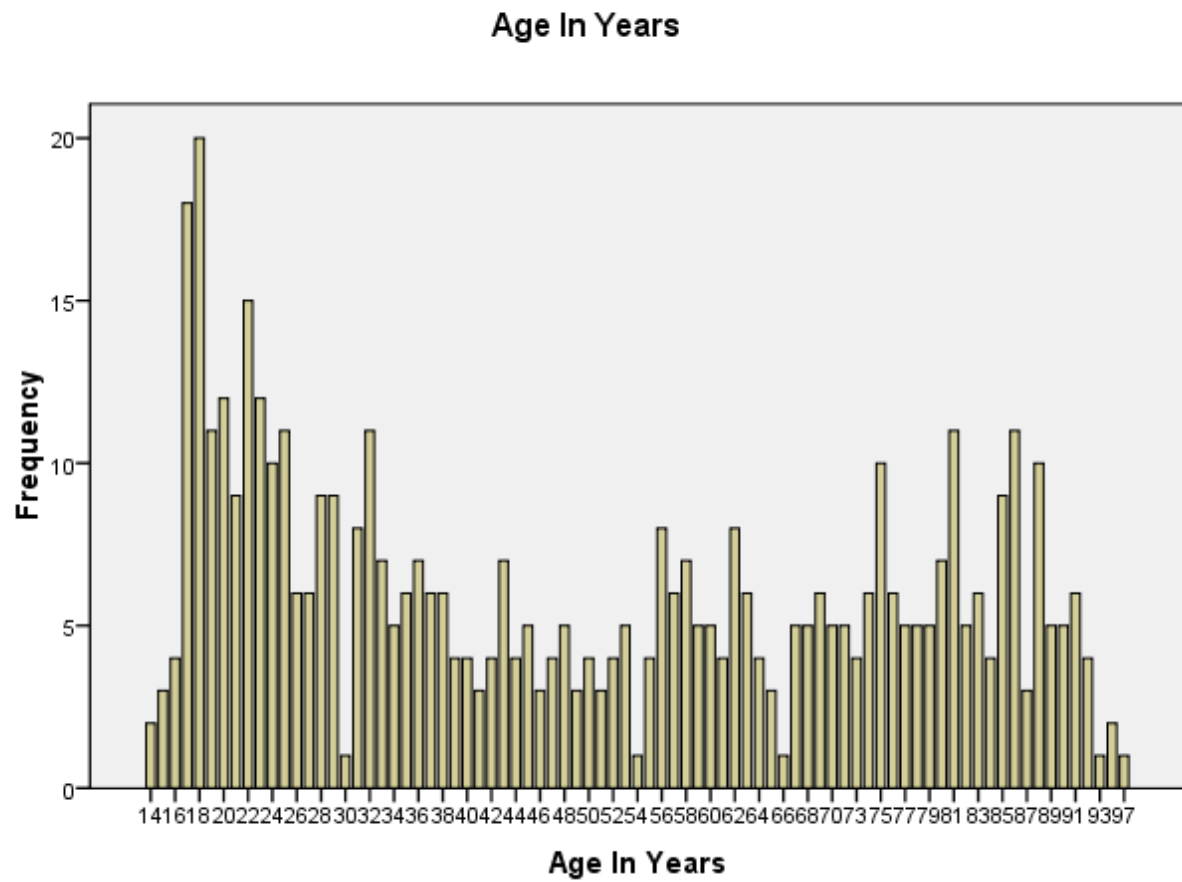


Figure 8. Response time

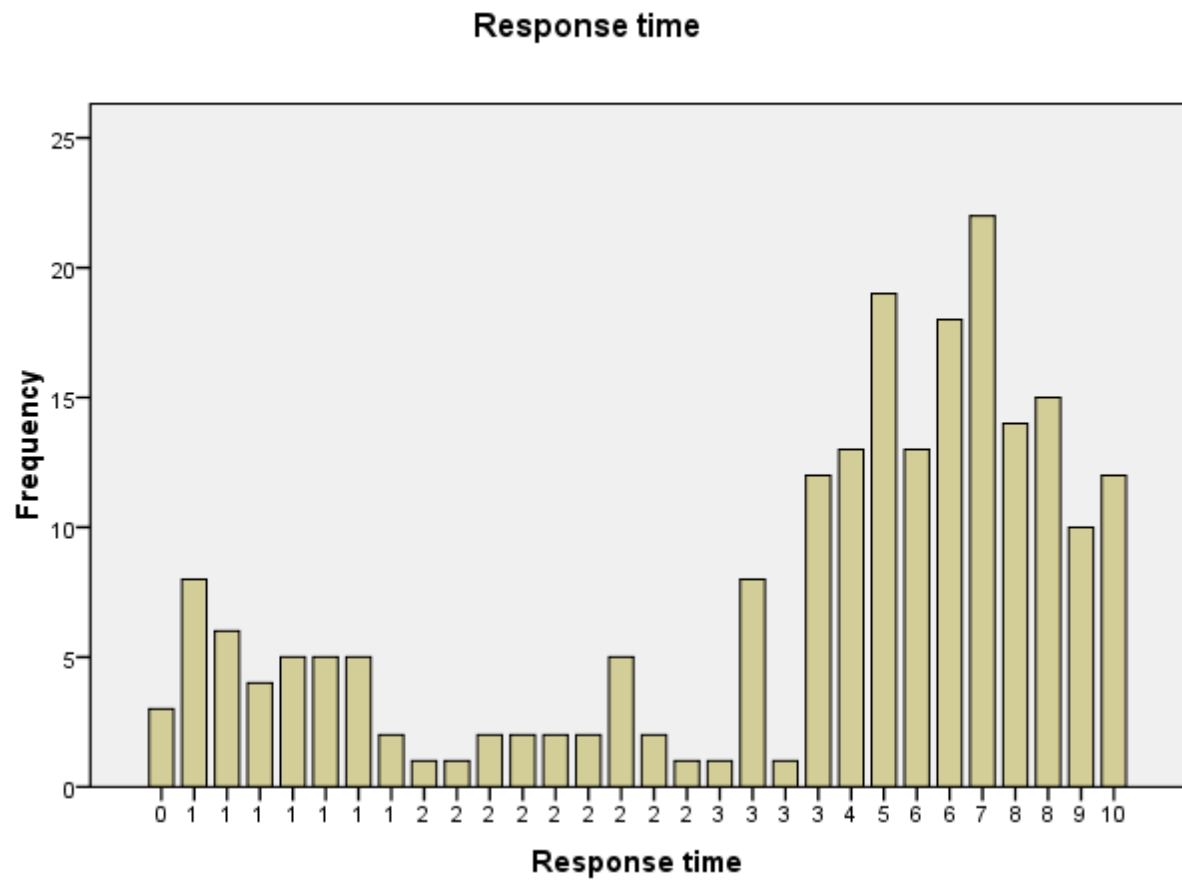
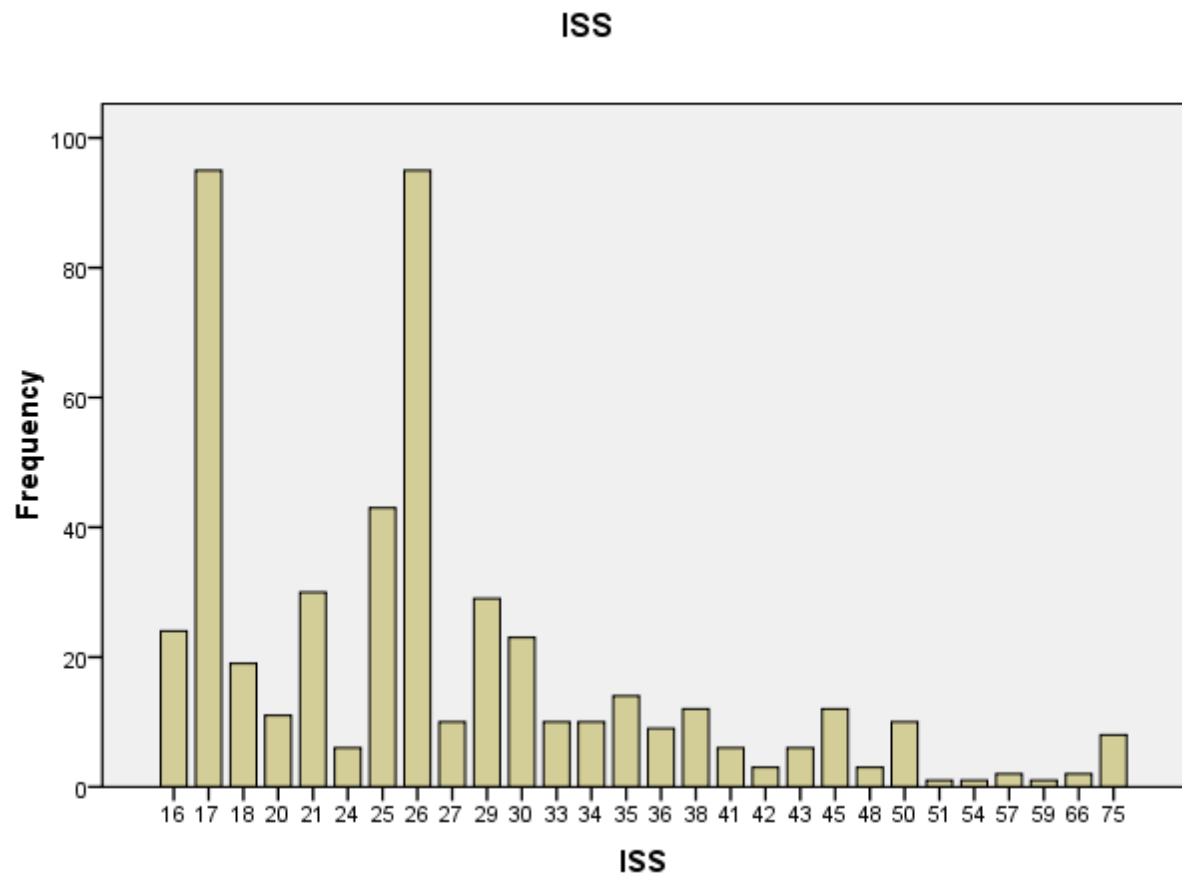


Figure 9. Injury Severity Score



MISSING VARIABLES

Missing values for variables (Response time [n= 281], Scene time [n=285], and final observation RTS [n= 165]) caused a large loss of participants in the analysis of the relationship between intubation status and mortality (table 4).

Table 4. Missing data

		Response time	Scene time	Initial Observation RTS	Final Observation RTS	ISS
N	Valid	214	210	425	330	495
	Missing	281	285	70	165	0

Furthermore as discussed previously the application of specific variables airway management and gender (tables 5 and 6) were not evenly distributed.

Table 5. Airway management utilised basic / advanced

	Frequency	Percent	Valid Percent	Cumulative Percent
Valid advanced	15	3.0	3.0	3.0
basic	480	97.0	97.0	100.0
Total	495	100.0	100.0	

Table 6. Gender

	Frequency	Percent	Valid Percent	Cumulative Percent
Valid Female	134	27.1	27.1	27.1
Male	361	72.9	72.9	100.0

Table 5. Airway management utilised basic / advanced

	Frequency	Percent	Valid Percent	Cumulative Percent
Valid advanced	15	3.0	3.0	3.0
basic	480	97.0	97.0	100.0
Total	495	100.0	100.0	

As a consequence a reliable logistical regression model could not be applied to the data set. To build an effective model for analysis, cases where advanced airway management was utilized were matched with cases where basic airway management was utilized. 15 cases where advanced airway management was applied were identified. For each of these, 4 cases where basic airway management was performed were matched by injury severity score and gender. As a consequence TRISS analysis, which combines these factors, was not used in the analysis. A binary logistic regression model was then applied utilising survival as the dependent variable and age, airway management, and initial GCS as predictor variables (table 7)

Table 7 Regression analysis

Classification Table ^a		Predicted
Observed		
		Percentage Correct
Step 1	Outcome survival = 1 death = 0	60.0
	0 1	96.4

	Overall Percentage	86.8
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Variables in the Equation

	B	S.E.	Wald	Df
Step 1 ^a Age	-.077	.046	2.761	1
Airway management utilised	2.186	1.298	2.838	1
Initial Observation GCS	.599	.240	6.216	1
Constant	-2.161	1.512	2.044	1

Variables in the Equation

	Sig.	Exp(B)
Step 1 ^a Age	.097	.926
Airway management utilised	.092	8.901
Initial Observation GCS	.013	1.820
Constant	.153	.115

This model demonstrated the most correct classification of cases as died or survived (87%). Airway management has a 2 sided p-value of 0.092 in this model. The one-tailed p-value is found by dividing this value by 2 (0.046). This presents a significant association that the use of advanced airway management increases odds of survival with an OR of 8.9. Unfortunately due to poor data quality this model could not be consistently applied to all variables detailed in the project plan. This also prevented achievement of the second aim of the project.

Discussion:

Early airway management is recommended because of the association between hypoxia, hypercarbia and worsened outcome after TBI. The paramedic must be aware of possible elevated ICP, probable full stomach, potentially difficult airway (blood, possible base of skull fractures, possible facial airway trauma), potential cervical spine injury, hypoxia and a possibly combative patient. Though the paramedic should try to initiate rapid transport to definitive care and minimise scene time, they must give priority to preventing hypoxia and hypotension, avoiding aspiration and protecting the cervical spine. A positive association was demonstrated in this research between airway management and outcome. This is significant in that many previous studies have found negative associations between airway management practice and survival. Further research is recommended to better determine efficacy of practice in treating this patient group.

Limitations:

Unfortunately findings were limited due to poor and/or incomplete data. With respect to the original aims and objectives of this research project, only analysis of association between survival and airway management utilisation could be performed due to the lack of completed pre hospital data. As a consequence, biostatistical analysis required considerable review and alteration, and the smaller sample size limits the validity of the findings. Furthermore, as the nature of this study is retrospective, the results cannot imply causality.

The study excluded patients that died before arrival to hospital and patients that deteriorated and subsequently received cardio pulmonary resuscitation before arrival to hospital. These cases

should have been included in the analysis as intention to treat. It is unknown whether these cases were evenly distributed between airway management groups.

Of all cases received for analysis none included RSI management by Critical care paramedics. This reflects inaccurate recording and data collection as it is known that cases occurred during this time period where this intervention was applied. St John Ambulance Australia WA Inc has introduced electronic patient care recording, it is expected that this will greatly improve organisational data capture. We do not have the ability to extract the site of intubation, the number of attempts, or more detail about the causes of morbidity or mortality from the database. Nor is it possible to ascertain level of skill or experience of officers. Additionally it is recognised that intubation is a difficult skill that can degrade with lack of currency in practice. As such, it carries a high level of risk when utilised for the airway management of patients suffering TBI. There is no data to reflect practitioner exposure to this skill between cases nor can it be determined whether the skill set was practiced without difficulty during attempts.

No data were collected on other less common forms of intubation, such as a temporary surgical airway.

Recommendations:

The findings of this study, whilst limited, provide the basis for service improvement in this area.

Recommendation 1: Development and maintenance of a pre hospital trauma registry that captures validated clinical data relevant to the outcome impact of Traumatic Brain Injury. A registry such as this would include the following variables:

1. Patient age and sex
2. Response time
3. Scene time
4. Transport time
5. Revised trauma score on first pre hospital assessment
6. Patient physiological measurements (GCS, heart rate, blood pressure, respiratory rate, SpO₂) on scene arrival, scene departure and hospital arrival.
7. Airway management utilised (basic, advanced or RSI)
8. Patient PaCO₂ measured by blood gas analysis on hospital arrival.
9. Patient injury severity score.
10. Patient trauma and injury severity score.
11. Patient survival to discharge

Recommendation 2: Development and maintenance of a clinical practice registry to better understand education and competence requirements for low use/ high risk interventions, and implement service programs to improve patient outcomes.

Recommendation 3: Current practice should continue until reliable data is established to better inform decision making.

Recommendation 4: Implementation of Ambulance service clinical auditing and early evaluation of high risk intervention usage to improve service documentation standards.

Conclusion:

Results of this study indicate a significant association between airway management practice performed by paramedics and survival for patients suffering TBI. Further research is recommended to accurately assess efficacy of practice of this skill set in the pre hospital environment.

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Appendix 1: Research process Summary.

